Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Schema Therapy Mode Model on Tension, Distress Tolerance and Executive Functions in patients with Psychosomatic Symptoms in Rasht city

Protocol summary

Study aim
Determining the Effectiveness of Schema Therapy Mode Model on Tension, Distress Tolerance and Executive Functions in patients with Psychosomatic Symptoms in Rasht.

Design
Randomized clinical trial with two experimental and control groups with single-sided blinding on 15 people (for each group)

Settings and conduct
Schema Therapy Mode Model intervention is implemented in a group setting at the Rasta Clinic in Rasht on 15 subjects in the experimental group.

Participants/Inclusion and exclusion criteria
The statistical population comprised psychosomatic patients (DSM-5 diagnosed) referred to Rasht medical centers in 2024, presenting physical complaints without identifiable medical etiology. Inclusion criteria were: moderate-to-high stress scores, absence of comorbid medical/psychiatric conditions, no psychotropic medication use, and no concurrent psychotherapy. Exclusion criteria included withdrawal from participation, onset of psychotic symptoms, >2 session absences, initiation of medication during the study, or incomplete questionnaire responses (>10% missing data).

Intervention groups
The experimental group in this study will undergo a Schema Therapy Mode Model intervention, which is implemented by an experienced therapist and under the direct supervision of an expert supervisor. The intervention protocol consists of 8 120-minute sessions, the content of which is adapted from Rosie Reubsaet's book entitled "Schema Therapy – A Phase-Oriented Approach: Targeting Tasks and Techniques in Individual and Group Schema Therapy."

Main outcome variables
Tension, Distress Tolerance, Executive Functions, Psychosomatic Symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250808066787N1**
Registration date: **2025-09-09, 1404/06/18**
Registration timing: **prospective**

Last update: **2025-09-09, 1404/06/18**
Update count: **0**

Registration date
2025-09-09, 1404/06/18

Registrant information
Name
Elham Rahmati Roudsari
Name of organization / entity
Islamic Azad University, Rasht Branch
Country
Iran (Islamic Republic of)
Phone
+98 13 4263 2169
Email address
e.rahmati.psy@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-21, 1404/06/30

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Schema Therapy Mode Model on Tension, Distress Tolerance and Executive Functions in patients with Psychosomatic Symptoms in Rasht city

Public title

The Effectiveness of Schema Therapy Mode Model on Tension, Distress Tolerance and Executive Functions in patients with Psychosomatic Symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Received a diagnosis of psychosomatic disorders and psychosomatic symptoms by a psychologist according to DSM-5 criteria and research questionnaire Achieving a minimum average score on the stress scale No specific medical problems (symptoms should not have a medical cause) Not taking psychiatric medications Not participating in other group treatments or individual psychological therapy at the same time as the study

Exclusion criteria:

Not willing to continue cooperation Having a psychotic disorder Absent more than two sessions Concurrent medication use Not completing more than 10% of the questions in the questionnaires

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

After collecting information from the target population, from the list of patients through systematic sampling, necessary contacts and coordination were made to attend the study and treatment sessions, and after that, the eligible samples, after being selected, will be allocated to two control and intervention groups through a simple random method. For concealment, we use Allocation Concealment, which refers to the method used to perform a random sequence on study participants in a way that the assigned group is not known before the individual is allocated. Using opaque sealed envelopes with a random sequence, in this method (Sealed, Sequentially, Envelopes, Numbered), each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain the random sequence, numbering is also done on the outer surface of the envelopes in the same order. Finally, the lids of the envelopes are glued and placed in a box in order. At the start of participant registration, based on the order in which eligible participants enter the study, one of the envelopes is opened in order and the assigned group of that participant is revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, the experimental group was administered a Schema Therapy Mode Model protocol for 8 2-hour sessions, but the control group did not receive any intervention (in order to comply with research ethics, the control group will receive the intervention after the study is completed). Valid questionnaires (valid and reliable) were used at all stages to measure Tension, distress tolerance, and executive functions of the subjects. In this study, one-way blinding was used, such that the participants were not aware of their allocation to the experimental or control groups. This was done by not disclosing the type of intervention to the participants and also by using the same instructions for completing the questionnaires. The researchers and therapists were aware of the grouping of the subjects, but the participants remained unaware of this until the end of the research process to prevent their expectations from affecting the results.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University-lahijan branch

Street address

Sarpol Sharqi, Valiasr Street, corner of Kharazmi Alley

City

Roudsar

Province

Guilan

Postal code

٤٤٨١٨٦٥٩٥٣

Approval date

2025-07-08, 1404/04/17

Ethics committee reference number

IR.IAU.LIAU.REC.1404.053

Health conditions studied

1

Description of health condition studied

Psychosomatic disorders

ICD-10 code
F50-F59
ICD-10 code description
Unspecified behavioural syndromes associated with physiological disturbances and physical factors

Primary outcomes

1

Description
Psychosomatic symptoms
Timepoint
Pre-test, post-test, follow-up
Method of measurement
Psychosomatic Complaints Inventory (PCI)

Secondary outcomes

1

Description
Tension
Timepoint
Pre-test, post-test, follow-up
Method of measurement
Perceived Stress Scale-10 (PSS-10)

2

Description
Distress Tolerance
Timepoint
Pre-test, post-test, follow-up
Method of measurement
Distress Tolerance Scale (DTS)

3

Description
Executive Function
Timepoint
Pre-test, post-test, follow-up
Method of measurement
Short Executive Function Scale (SEFS)

Intervention groups

1

Description
Intervention group: Mindfulness-based schema therapy (STMM); The statistical population of this study consists of psychosomatic patients in Rasht city treatment centers in 1404. 30 people from the aforementioned population will be randomly selected and allocated to two groups (15 people in the experimental group and 15 people in the control group). The following protocol and tools will be used in relation to the therapeutic intervention and data collection: The experiment in this study is called Mindfulness-based schema therapy intervention, which is implemented by an experienced therapist and under the direct supervision of an expert supervisor. The intervention protocol consists of 8 120-minute sessions, which is based on Rosie Robesy's book entitled "Stage-Based Schema Therapy: Goal Setting, Tasks, and Techniques in Individual and Group Schema Therapy." All participants complete a standard questionnaire consisting of demographic information items, Takata and Sakata Psychosomatic Disorders Questionnaire, Short Executive Functioning Scale (SEFS) for Work, Cohen's Perceived Stress Scale (PSS-10), and Simmons and Gahr Distress Tolerance Scale as a pre-test, and the experimental group undergoes mindfulness-based schema therapy training. They are provided with a consent form to participate in the study, and necessary explanations are provided about the purpose and structure of the treatment, the emphasis on completing assignments, and how the sessions are held, and the questions and ambiguities of the people present in the study are answered. Therefore, the participants are mentally prepared to attend the treatment sessions, and a post-test will be administered after the end of the intervention period. A 45-day follow-up period is also conducted to determine the sustainability of the treatment effects.
Category
Treatment - Other

2

Description
Control group: The statistical population of this study consists of psychosomatic patients attending medical centers in Rasht in 1404. 30 people from the aforementioned population will be randomly selected and assigned to two groups (15 in the experimental group and 15 in the control group). All participants will complete a standard questionnaire consisting of demographic information items, Takata and Sakata Psychosomatic Disorders Questionnaire, Short Executive Function Scale (SEFS) of Work, Cohen's Perceived Stress Scale (PSS-10), and Simmons and Gaher Distress Tolerance Scale as a pre-test; but the control group will not be trained in mindfulness-based schema therapy. They will be provided with a consent form to participate in the study, and the necessary explanations will be provided regarding the purpose and structure of the study, emphasizing the method of conducting the research stages, and the questions and ambiguities of the people present in the study will be answered. Therefore, the participants will be mentally prepared to participate in the study, and a post-test will be administered after the end of the study. A 45-day follow-up period will also be conducted to determine the sustainability of the treatment effects. (To comply with research ethics, the control group will receive the intervention after the research is completed).
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasta Counseling and Psychotherapy Center

Full name of responsible person
Zeenat Sadat Mirpur

Street address
Ziabari Blvd. 2, before the underpass, next to Dar Al-Marz School, Block 3, Unit 13, 6th Floor

City
Rasht

Province
Guilan

Postal code
۴۱۵۷۹۵۷۳۱۹

Phone
+98 13 3200 5565

Email
zinat.mirpoor@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University, Rasht Branch

Full name of responsible person
Alireza Saydavi

Street address
Lacan's Gate - Islamic Azad University, Rasht Branch

City
Rasht

Province
Guilan

Postal code
۴۱۴۷۶۵۴۹۱۹

Phone
+98 13 3342 3308

Email
info@iaurasht.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University, Rasht Branch

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mojgan Asadi Louyeh

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
End of Shaghayegh Street, Islamic Azad University of Lahijan

City
لاهیجان

Province
Guilan

Postal code
1616

Phone
+98 13 4122 9081

Email
m_asadi69@yahoo.com

Web page address
https://lahijan.iau.ir/fa

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mojgan Asadi Louyeh

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
End of Shaghayegh Street, Islamic Azad University of Lahijan

City
Lahijan

Province
Guilan

Postal code
1616

Phone
+98 13 4122 9081

Email
m_asadi69@yahoo.com

Web page address
https://lahijan.iau.ir/fa

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University, Rasht Branch
Full name of responsible person
Elham
Position
Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Gilan, Rudsar, Sarpol East, Valiasr Boulevard, Kharazmi Alley, corner of the commercial and residential building
City
Roudsar
Province
Guilan
Postal code
٤٤٨١٨٦٥٩٥٣
Phone
+98 13 4263 2169
Email
e.rahmati.psy@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the sensitive and confidential nature
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only codes processed in statistical analysis can be published
When the data will become available and for how long
There are no plans to publish research data and the data will remain confidential.
To whom data/document is available
Only research researchers have access to the data.
Under which criteria data/document could be used
For the purpose of statistical analysis and reality testing of research results
From where data/document is obtainable
Research data is only available to the researchers of the present study and can be processed through them.
What processes are involved for a request to access data/document
By sending a request and communicating with the researchers of this study
Comments